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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,510	02/08/2002	Edwin Clark	MRI-027	3451
959	7590	03/23/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			RAWLINGS, STEPHEN L	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/071,510

**Applicant(s)**

CLARK ET AL.

**Examiner**

Stephen L. Rawlings, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2004 and 18 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 15-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The amendment filed October 18, 2004 is acknowledged and has been entered.
2. The election filed June 29, 2004 is acknowledged and has been entered. Applicant has elected the invention of Group I, claims 1-14, insofar as the claims are directed to a method for determining whether an agent can or cannot be used to reduce the growth of a tumor comprising determining whether the tumor cells express the sensitivity marker of SEQ ID NO: 16.

Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 1-69 are pending in the application. Claims 15-69 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
4. Upon additional consideration of the claims of the elected group, claims 1-14 are now subject to further restriction.

### ***Election/Restrictions***

5. This application contains claims 1-14 of Group I, which are directed to patentably distinct species of the claimed invention, wherein said agent is selected from the group consisting of (a) a taxane compound, (b) a platinum compound, and (c) a combination of agents consisting of a taxane compound and a platinum compound.

Each species of invention, wherein the agent is a different species of agent, is patentably distinct, each from the others, for the following reasons:

It is recognized that the claimed invention requires a correlation between the level of expression of the sensitivity marker of SEQ ID NO: 16 in a tumor and the ability

of each different species of agent to reduce the growth of that tumor. A tumor that is responsive to a taxane compound may not be sensitive to a platinum compound, and visa versa. Furthermore, the effects of a combination of agents, such as a taxane compound and a platinum compound can be synergistic, additive, or subtractive in nature, depending upon whether and how one compound affects the activity of the other. If a combination is effective, it cannot be reliably predicted or determined if the individual agents are also effective, without also determining the individual effects of each agent in the absence of the other. If the combination is not effective, it cannot be predicted or determined if the individual agents alone are also ineffective, without also determining the individual effects of each agent in the absence of the other. Moreover, the level of a given marker, such as the "sensitivity marker" of SEQ ID NO: 16 may correlate with the degree of sensitivity of a tumor to one agent or the other, or it may correlate with the degree of sensitivity to a combination of the agents. The level of expression of the marker does not necessarily correlate with every agent or combination of agents. Accordingly, the skilled artisan would not attempt to determine whether one or the other agent of a combination of agents can be used to reduce the growth of a tumor by determining the expression of a marker that correlates with the ability of a combination of agents to reduce the growth of the tumor. Due to these operable differences in the different species of the claimed invention, the search and considerations required to examine the claims to the extent that the claims are directed to any one species is not the same, nor is it coextensive with that required to examine claims directed to the other species. Therefore, each different species of invention requires a separate and unique search and different considerations, which will not provide adequate information regarding any other. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the agent to which the claims of the elected invention are to be directed, which species of invention will be considered for prosecution on the merits and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that the presence of one novel and nonobvious species of invention would render the claims, insofar as those claims are drawn to that species,

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allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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**Conclusion**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
March 21, 2005